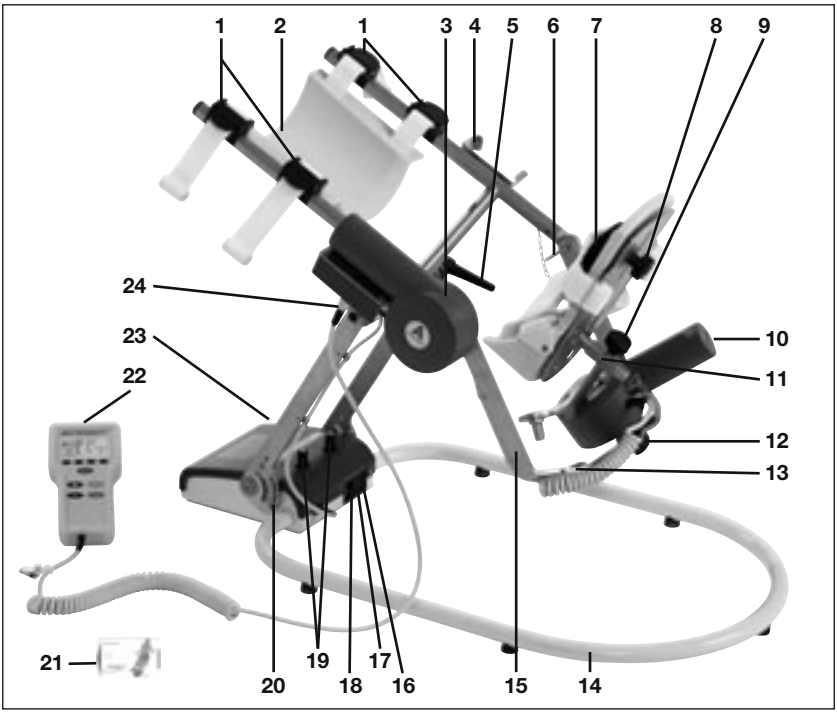
ARTROMOT®-SP3

D **Gebrauchsanweisung**
USA/GB **Operation Manual**
F **Mode d'emploi**
E **Instrucciones para el uso**
I **Istruzioni per l'uso**
NL **Gebruiksaanwijzing**

Gerätebeschreibung

Device description
Description de l’appareil
Desripción del aparato
Descrizione dell’apparecchiatura
Gebruikershandleiding



Contents

Description of the ARTROMOT®-SP3 System 3

ARTROMOT®-SP3 setup illustrations 224

Symbol overview 221

1. How to use the CPM device 41

1.1 Fields of application 41
1.2 Therapy objectives 41
1.3 Indications 41
1.4 Contraindications 41

2. Description of the ARTROMOT®-SP3 42

2.1 Description of the device components 42
2.2 Description of the programming unit 43
2.3 Explanation of symbols 46
2.4 Explanation of symbols (connections and nameplate) 47

3. Safety information 48

4. Device setup 51

4.1 Connecting the device, performance check 51
4.2 Adjusting the device to the patient 52

5. Setting the treatment values 54

5.1 General information on programming ARTROMOT®-SP3 54
5.2 Programming ARTROMOT®-SP3 Standard 55
5.3 Treatment value details – Standard models 56
5.4 Programming ARTROMOT®-SP3 Comfort 60
5.5 Protocol details – Comfort models 60

6. Care, Maintenance, Transport, Conversion 65

6.1 Care 65
6.2 Maintenance (fuse replacement) 65
6.3 Transport 66
6.4 Conversion 67

7. Environmental Protection Statement 68

8. Specifications 68

9. IEC 60601-1-2:2001 69

9.1 Electromagnetic emissions 69
9.2 Electromagnetic immunity 70
9.3 Recommended Separation Distances 72

10. Contact 72

11. Technical service 73

11.1 Technical Hotline 73
11.2 Shipment 73
11.3 Spare Parts 73

12. Declaration of conformity 74

1. How to use the CPM device

1.1 Fields of application

ARTROMOT®-SP3 is a motor-operated **C**ontinuous **P**assive **M**otion (**CPM**) device providing motion to the ankle joint.

Suitable for use in hospitals, clinics, general practices and rental services, it is an important supplement to medical and therapeutic treatment.

1.2 Therapy objectives

CPM therapy with **ARTROMOT®-SP3** is mainly used to prevent the negative effects of immobilization, to allow patients to regain painless mobility of joints at an early stage and to promote healing and achieve a positive functional result.

Other objectives of therapy include:

- improvement of joint metabolism
- prevention of joint stiffness
- promotion of the regeneration and healing of cartilage and damaged ligaments
- faster hematoma/fluid resorption
- improved lymph and blood circulation
- thrombosis and embolism prophylaxis

1.3 Indications

The CPM device is indicated in the treatment of most injuries and diseases of the ankle joint as well as in the post-operative treatment after joint surgery and in the treatment of joint diseases. Examples:

- joint distortion and contusion
- arthrotomy and arthroscopy procedures in combination with synovectomy, arthrolysis or other intra-articular interventions
- mobilization of joints in anesthetized patients
- exercise-stable fractures after surgery, pseudoarthrosis and osteotomy
- myoplasty
- arthroplasties including implantation of endoprostheses

1.4 Contraindications

Do NOT use ARTROMOT®-SP3 on patients with:

- acute inflammatory processes in the joints, unless on the order of a physician
- spastic paralysis
- unstable osteosynthesis

2. Description of the ARTROMOT®-SP3

The motorized CPM device provides the following passive motion to the ankle joint:

plantar flexion / dorsal extension
50° / 0° / 40°

inversion / eversion
40° / 0° / 20°

It can be reconfigured for use on either side and allows patients to exercise in bed and while sitting on a chair.

Note!

To unambiguously represent the current position of the CPM device, the values for plantar flexion and inversion are marked with the symbol "-" both on the display and in this document.

These are some of the **ARTROMOT®-SP3** features:

- anatomically correct setup
- physiological movements
- programming unit for precise adjustment of patient-specific therapy values
- symbols for easy operation of the programming unit
- chip card for storage of the programmed therapy parameters

Biocompatibility

Those parts of the **ARTROMOT®-SP3** device that come into contact with the patient when the device is used as intended, are designed to fulfil the biocompatibility requirements of the applicable standards.

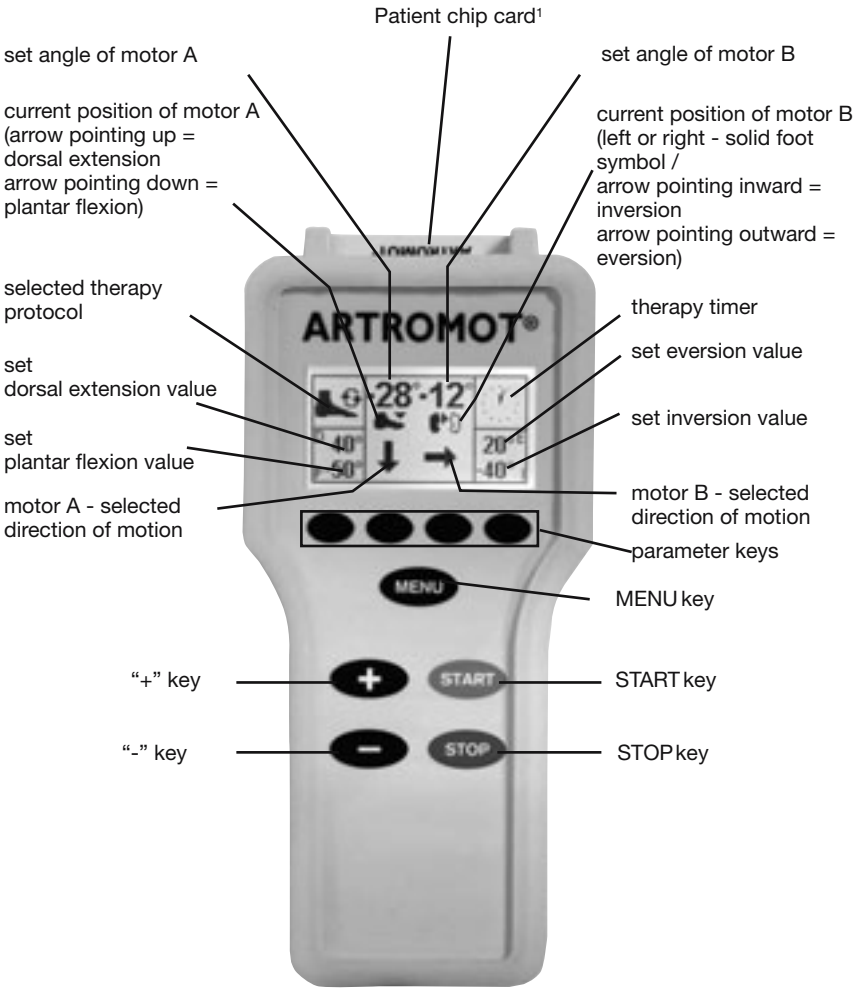
2.1 Description of the device components

Note: Please fold out page 3!

1. Clamping levers to adjust the height of the calf support assembly
2. Calf support assembly
3. Motor A (center of rotation for dorsal extension/plantar flexion)
4. Bracket for programming unit
5. Clamping lever to adjust the inclination of the carriage
6. Aiming pin for adjustment of the rotational axis of the upper ankle joint
7. Footplate
8. Knurled screw for adjustment of the footplate height
9. Knurled screw to adjust the footplate to the leg length
10. Motor B
11. Footplate bracket
12. Thumbscrew to secure motor B on the moving bracket for dorsal extension / plantar flexion
13. Bore hole to mount motor B to the moving bracket for dorsal extension/ plantar flexion
14. CPM base
15. Moving bracket for dorsal extension/ plantar flexion
16. Power switch (ON/OFF)
17. Fuse cap
18. Connection for power cord
19. Locking device to adjust the height of the carriage
20. Perforation to set the height of the carriage
21. Patient chip card[1]
22. Programming unit
23. Nameplate
24. Connection for programming unit

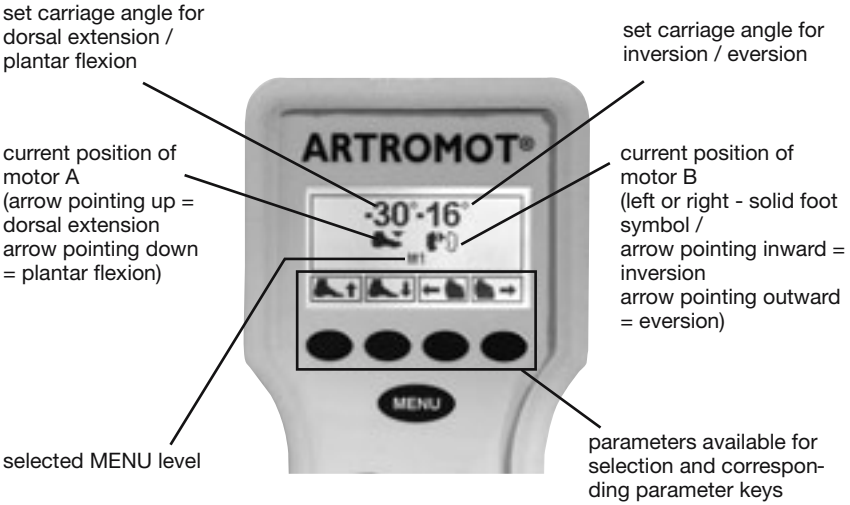
2.2 Description of the programming unit

2.2.1 Programming unit in normal mode

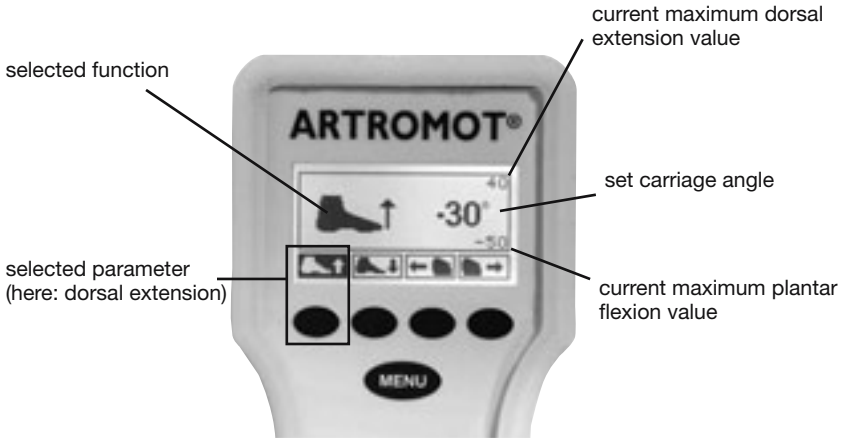


[1]Devices of the **ARTROMOT®-SP3** product family **with patient chip card** only

2.2.2 Programming unit in MENU selection mode


set carriage angle for dorsal extension / plantar flexion
set carriage angle for inversion / eversion
current position of motor A (arrow pointing up = dorsal extension arrow pointing down = plantar flexion)
current position of motor B (left or right - solid foot symbol / arrow pointing inward = inversion arrow pointing outward = eversion)
selected MENU level
parameters available for selection and corresponding parameter keys
ARTROMOT®
-30°-16°
MENU

2.2.3 Programming unit set to ROM programming



2.2.4 Programming unit in general programming mode

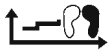
2.3 Explanation of symbols

Also refer to symbol overview on page 221

Standard protocols:

	dorsal extension
	plantar flexion
	inversion
	eversion
	pause
	timer
	speed
	new patient
	load reversal motor A
	load reversal motor B
	motor A ON/OFF
	motor B ON/OFF
	transport setting
	synchronized/non-synchronized mode
	total therapy time
	service menu

Comfort protocols:

	warm up protocol
	isolation protocol
	dorsal extension / plantar flexion therapy documentation
	inversion / eversion therapy documentation
	stretching in dorsal extension
	stretching in plantar flexion
	stretching in inversion
	stretching in eversion

2.4 Explanation of symbols (connections and nameplate)

	alternating current
	protective earth connection
	type B applied part
	power switch OFF
	power switch ON
	Refer to accompanying documents
	Do not dispose of product with unsorted household or municipal waste.

3. Safety information

Definitions

It is mandatory to read the safety statements before use of the CPM device. The safety statements are classified as follows:

⚠ Danger

This term indicates an imminent hazard. If not avoided, this hazard will result in death or serious injury.

⚠ Warning

This term indicates a hazard. If not avoided, this hazard can result in death or serious injury.

⚠ Caution

This term indicates a potential hazard. If not avoided, this hazard can result in minor personal injury and/or product/property damage.

Safety information

⚠ Danger

Explosion hazard –

ARTROMOT®-SP3 is not designed for use in areas where an explosion hazard may occur. An explosion hazard may result from the use of flammable anesthetics, skin cleansing agents and disinfectants.

⚠ Warning

Patient hazard –

- Only authorized individuals are allowed to operate the **ARTROMOT®-SP3** device. Individuals are authorized after receiving training in the operation of the device and reading this operation manual.
- Before using the device, the operator must ascertain that it is in correct working order and operating condition. In particular, the cables and connectors must be checked for signs of damage. Damaged parts must be replaced immediately, before use.
- **Before therapy**, a **test run** consisting of several exercise cycles must be completed, first without and then with the patient. Check that all setting screws are tightened.
- Stop therapy immediately, when you have doubts about the device settings and/or the therapy protocol.

- It is important that the patient's position is **anatomically correct**. Therefore, carefully verify the following settings/positions:

1. carriage angle
2. ankle joint axis/carriage axis motor A
3. Footplate adjustment
4. Calf support assembly

- Movements must **not** cause **any pain or irritation**.

- Patients must be fully conscious while being instructed in the use of the CPM device and during therapy.

- The **choice** of the **therapy parameters** to program and of the **therapy protocols** to use is **restricted to** the responsible **physician or therapist**. It is the physician's or therapist's decision whether or not to use the CPM device on a specific patient.

- The patient must be familiar with the functions of the **ARTROMOT®-SP3** programming unit and the unit must be **within easy reach** of the patient, allowing him or her to stop therapy, if needed. **Patients unable to operate the programming unit**, e.g. paralytic patients, must never be left unattended during therapy.

- After data storage, write the patient's name on the **patient chip card**[1]. The card should only be used for this patient. If the **patient chip card**[1] is used for another patient, be sure to **delete the previous patient's data** from the card first (see: section 5.3, “New patient”).
[1]Use original chip cards only .

- All **accessories** used with the **ARTROMOT®-SP3** device must first be approved by ORMED.

- Do not allow **parts of the body or any objects** (such as blankets, cushions or cables) to get caught **in the moving parts** of the CPM device.

[1] Devices of the **ARTROMOT®-SP3** product family **with patient chip card** only.

⚠ Warning

Shock hazard –

Strictly observe the following warnings. Failure to do so endangers the lives of the patient, the user and other persons involved.

- **Before** use allow the ARTROMOT®-SP3 to reach room temperature. If the device has been transported at temperatures below 0 °C (32°F), leave it to dry at room temperature for about 2 hours, until any condensation has disappeared.

- The ARTROMOT®-SP3 device must only be operated in **dry rooms**.

- When disconnecting the device from the power line, remove the plug from the wall outlet first, before disconnecting the cable from the device.

- When connecting the device to other equipment or when creating a medical system, check that the sum of leakage currents will not cause any hazard. Please contact ORMED, if you have questions in this matter.

- Do not use multiple portable socket outlets (MPSO) to connect the device to the power line. ARTROMOT®-SP3 must be connected to a **properly installed wall outlet with a non-fused earthed wire**. Before connecting the power cord, it must be completely unrolled and placed such that it will not get caught in the moving parts of the device.

- **Before cleaning and service interventions, disconnect the device** from the power line by removing the power cord from the wall outlet.

- Liquids must not be allowed to enter the CPM device or the programming unit. If liquids have entered into the devices, ARTROMOT®-SP3 must be immediately checked by a service technician, before it can be reused.

⚠ Warning

Equipment malfunction –

- Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the CPM device comply with the relevant EMC requirements. X-ray equipment, MRI devices, radio systems and cell phones are possible sources of interference as they may emit higher levels of electromagnetic radiation. Keep the CPM device away from these devices and verify its performance before use.
- Refer **repair** and **maintenance** to authorized persons.
- **Route all cables below the device frame to either side**, ensuring that they cannot get caught in the moving parts during operation.
- Inspect ARTROMOT®-SP3 for damage and loose connections at least **once a year**. Damaged and worn parts must immediately be replaced with original spare parts by authorized staff.

⚠ Caution

Preventing chafing and pressure sores – If your patient is **adipose**, very **tall** or **very short**, be sure to prevent chafing and pressure sores. Place the leg concerned in a moderate abductive position, if deemed appropriate.

⚠ Caution

Equipment damage –

- Check that the voltage and frequency ratings of your local **power line** are those indicated on the nameplate.
- The leg support element withstands a **maximum continuous load** of **20 kg**.
- Do not allow **any objects** (such as blankets, cushions, or cables) to get caught in the **moving parts** of the CPM device.
- Do not expose the ARTROMOT®-SP3 device to direct sunlight, because some of the components may reach inadmissibly high temperatures.

4. Device setup

Note: For a better understanding of each step, please fold out pages 3 and 224.

4.1 Connecting the device, performance check

1. Connect the **power cord** to socket (18) of the device and connect the **mains plug** to a wall outlet with a non-fused earthed wire (100 to 240 Volt, 50/60 Hz).
2. Turn the **power switch** (16) on.

⚠ Caution

Equipment damage Be sure to lift the moving bracket for dorsal extension / plantar flexion (15) a little, relieving the strain on it, before you either press the locking pins for the height adjustment together or loosen the clamping lever for adjustment of the inclination (5).

3. Release the locking device (19). To do so, first relieve the strain on the carriage by lifting the moving bracket for dorsal extension / plantar flexion (15) a little. Then press the two black pins of the locking device together simultaneously (Fig. A).
4. Set the carriage to an angle of approx. 60°, then release the pins of the locking device. Check that the pins engage in the perforation (20).
5. Again, hold the moving bracket for dorsal extension / plantar flexion (15) and release the clamping lever for adjustment of the inclination (5). Then lower the moving bracket for dorsal extension / plantar flexion (15) until it forms an angle of 45° with the base. Close the clamping lever to lock the carriage in that position (Fig. B).
6. Follow these steps to set the carriage to the home position

ARTROMOT®-SP3 without patient chip card

Press the **MENU** key on the programming unit twice to access programming level 2 (with each key press, you advance one level).

Press the “new patient” →0← parameter key and select this function (a check mark appears in the circle next to the function).

Press the **START** key. The CPM device automatically enters the **home position**.

ARTROMOT®-SP3 with patient chip card

- **Initial adjustment for new patients**

  Insert the original patient chip card (21) into the programming unit (22).

  Press the **MENU** key on the programming unit three times to access programming level 3 (with each key press, you advance one level).

  Press the “new patient” →0← parameter key and select this function (a check mark appears in the circle next to the function).

  Press the **START** key. The CPM device automatically enters the **home position**.

- **Adjustment with programmed chip card**

  Insert the original patient chip card (21) into the programming unit (22).

  Press the **START** key.

  The CPM device automatically enters the **home position**.

Performance check

If the programming unit can be operated as described above and **ARTROMOT®-SP3** enters the home position (for home position values, refer to sections 5.3 and 5.5), the device has passed the performance check.

The device also runs performance checks regularly during operation. This is what happens, if a problem is identified:

– An audio signal sounds.

– The device switches off immediately.

– The message "ERR", accompanied by a code number (e.g. ERR 5), appears on the display.

In this situation, you may attempt to restart the device by turning it briefly off and on again with the power switch. If the error message persists, have the device inspected by a Service technician, before using it again.

4.2 Adjusting the device to the patient

Before any treatment is possible, adjust the device as follows:

1. Before you adjust the ARTROMOT®- SP3 to the patient, you may have to convert the device for use on the left or right foot (see section 6.4 Conversion).
2. First lift the moving bracket for dorsal extension / plantar flexion (15) a little to hold it securely and to remove the strain. Simultaneously press the two black pins of the locking device (19) together. Now you can adjust the carriage to the correct height. Release the pins of the locking device (19). Check that the pins engage in the perforation (20) (Fig. A).
3. Continue to hold the moving bracket for dorsal extension / plantar flexion (15) and release the clamping lever for adjustment of the inclination (5). Adjust the correct inclination for the carriage. Close the clamping lever to lock the carriage in that position (Fig. B).
4. Place the patient's leg on the carriage and adjust the footplate (7) to the length of the patient's leg. To do so, loosen the knurled screw (9) and adjust the footplate accordingly. It is the purpose of this setting to adjust the rotational axis of the CPM device to the compromise center of rotation of the upper ankle joint. Check that the foot is firmly positioned against the footplate. Tighten the knurled screw (9) (Fig. C).
5. Loosen the clamping lever adjusting the height of the calf support assembly (1) (Fig. D) and the knurled screw adjusting the height of the footplate (8) (Fig. E). Set the calf support assembly and the footplate to a level where the rotational axis of the carriage and the compromise center of rotation of the upper ankle joint coincide. Close the clamping lever (1) and tighten the knurled screw (8) (Fig. D).
6. Check the settings and make sure that the patient is comfortably positioned. If necessary, repeat steps 2 to 5 to achieve a perfect setup.

Note!

- The aiming pin (6) is a valuable aid in adapting the carriage's rotational axis to the compromise center of rotation of the upper ankle joint. It identifies the correct compromise axis (Fig. F).
- If the CPM device is to be used on a supine patient, it is recommended to select a hip angle of approx. 40° at the ARTROMOT®-SP3.

⚠ Caution

Equipment damage –

- Cover the **leg support assemblies with disposable tissues**, when using the ARTROMOT®-SP3 immediately after surgery. This helps prevent discoloration.
- Before you change the carriage's inclination and/or height, always lift the moving bracket for dorsal extension / plantar flexion a little.

⚠ Caution

Patient hazard –

- Ensure that the rotational axes of the carriage and of the ankle joint coincide both in the vertical and in the horizontal plane (Fig. F).
- Before you change the carriage's inclination and/or height, always lift the moving bracket for dorsal extension / plantar flexion a little.

5. Setting the treatment values

⚠ Warning

Patient hazard –

Before therapy, a test run consisting of several exercise cycles must be completed without the patient. Then repeat the test run with the patient and check that the movement does not cause any pain.

Note!

See also 2.2 and 2.3 as well as page 221!

5.1 General information on programming ARTROMOT®-SP3

1. You activate the programming mode by briefly pressing the **MENU** key on the programming unit.
2. The treatment parameters and functions are allocated to four (Standard model) or six (Comfort model) programming levels (four per level).

   To be able to program a parameter you will have to access the corresponding programming level. This is also done with the **MENU** key. With each key press you advance one level. The code M1, M2, etc. that appears in the middle of the display indicates the programming level.
3. You activate the treatment parameters and functions with the **four parameter keys** below the display. The symbols above the four parameter keys indicate the assigned parameters and functions.

   This is what happens when you press one of the parameter keys to select a parameter:

   - The corresponding symbol appears on the display in a larger format.
   - The set value is displayed.
   - The symbol above the parameter key appears in reverse video.
4. With the **+** / **-** keys (plus/minus) you change the displayed value. When you press and hold the key, the value will change at a higher rate.

   Some of the (special) functions can only be enabled and disabled. This is done by pressing the corresponding parameter key or with the + / - keys. Active parameters are identified with a check mark in the circle next to the symbol.
5. Having programmed all parameters, press the **STOP** key to save the values.
6. Then press the **START** key: ARTROMOT®-SP3 will check the set values, it moves to the middle position and stops.
7. Press the **START** key again to start therapy.

   In the **synchronized mode**, the carriage will then move from the middle position to the maximum eversion value. Afterwards, the carriage will simultaneously move to the maximum inversion value and to the maximum plantar flexion value, and then simultaneously to the maximum dorsal extension value and the value halfway between inversion and eversion. After reaching this position, the cycle restarts: maximum eversion at the same time as halfway between dorsal extension / plantar flexion, etc.

   After activation of the START key in the **non-synchronized mode** the motors will perform random movements, each motor reversing after reaching the maximum values.

Note!

- Refer to sections 5.3 and 5.5 for a description of the parameters.
- To **view** the set **parameter values**, press the corresponding parameter key. Before, however, you have to press the STOP key and access the correct menu level.
- To prevent accidental changes of the parameter settings, **lock the keys** by simultaneously pressing the **+ (plus)** and **– (minus)** keys.

Press both keys again to unlock.

- Selecting the "New Patient" function will automatically delete the data on the patient chip card. When you have finished programming the unit and press the **STOP** key, the settings will automatically also be saved to the patient chip card.
- **Emergency stop function:** ARTROMOT®-SP3 will stop immediately, when any of the keys is pressed during therapy. When the START key is pressed in the **synchronized mode**, the carriage will move to the position halfway between the set values, and stops. Patient treatment can be resumed by pressing the START key. When the START key is pressed again in the **non-synchronized mode**, the carriage will reverse its direction.

Patients with a programmed chip card

- First complete the mechanical adjustments.
- Then insert the chip card (the patient is not yet positioned on the CPM device).
- Press the START key: the device will move to the middle position of the parameters stored on the chip card and stops.
- Position the patient on the CPM device and press the START key to initiate therapy.

5.2 Programming ARTROMOT®-SP3 Standard

To program the different settings of the **ARTROMOT®-SP3 Standard**, access the respective programming level.

You change between levels by pressing the **MENU** key.

The display always indicates the currently selected level.

The following **treatment values, settings** and **information** can be entered/viewed on the programming unit (22):

LEVEL 1:

- dorsal extension
- plantar flexion
- inversion
- eversion

MENU

LEVEL 2:

- pause
- therapy timer
- speed
- new patient

MENU

LEVEL 3:

- reverse on load - motor A
- reverse on load - motor B
- motor A ON/OFF
- motor B ON/OFF

MENU

continued on next page

LEVEL 4:

- transport setting
- synchronized/ non-synchronized mode A+B
- total therapy time
- service menu

Note!

- **While you adjust the** extension/flexion values, the carriage will move to the set range. This allows you to easily and quickly determine the ROM where the patient does not experience any pain.
- Special functions can be programmed and retrieved with **ARTROMOT®-SP3 Comfort** devices (see sections 5.4 and 5.5).
- Only **ARTROMOT®-SP3** chip card models allow therapy protocols to be **saved** to an inserted chip card.
- The angle entered last for the respective directions of motion will be saved in each case.

5.3 Treatment value details – Standard models

- To access the programming level you need, press the **MENU** key repeatedly.
- The treatment parameters are selected with the different **parameter keys**.
- To change the treatment values, press the + / – keys.
- To enable/disable a function, press the respective **parameter** key again.
- To save the entered values, press the **STOP** key.

LEVEL 1

■ **dorsal extension**

maximum value: **40 degrees**

■ **plantar flexion**

maximumvalue: **- 50 degrees**

■ **inversion**

maximum value: **- 40 degrees**

■ **eversion**

maximum value: **20 degrees**

Note!

- The programmed values and the values measured at the patient's foot may deviate slightly.
- To ensure a physiological motion, the carriage moves to the following positions in the synchronized mode in the following sequence:

  maximum dorsal value at the same time as halfway between inversion/eversion

  maximum eversion value at the same time as halfway between dorsal extension / plantar flexion

  maximum plantar flexion at the same time as maximum inversion

- To ensure that the movements you program are physiological in nature, we recommend to program the carriage in the following order:

1. Programming the maximum dorsal extension value
2. Resting the foot by programming a plantar flexion of 0°
3. Programming the maximum eversion value

4. Resting the foot by programming an inversion of 0°

5. Programming the maximum plantar flexion value

6. Programming the maximum inversion value

- When the **START** key is pressed in the synchronized mode, the device will first move from the middle position to the maximum eversion value. Afterwards, the carriage will simultaneously move to the maximum inversion value and to the maximum plantar flexion value, and then simultaneously to the maximum dorsal extension value and to the value halfway between inversion and eversion. After reaching this position, the cycle restarts: maximum eversion at the same time as halfway between dorsal extension / plantar flexion, etc.

LEVEL 2

■ **pauses**

Pauses occur at each programmed maximum value.

These are the **three pause points**:

maximum dorsal value at the same time as halfway between inversion / eversion

maximum eversion value at the same time as halfway between dorsal extension / plantar flexion

maximum plantar flexion at the same time as maximum inversion

Pauses can be set to any value between 0 and 59 seconds in steps of 1 second, and to values between 1 and 59 minutes in steps of 1 minute.
default setting: no pause

■ **therapy timer**

Default setting is continuous operation.

A clock symbol in the upper right-hand corner of the display identifies the continuous mode of operation. The clock indicates the elapsed therapy time.

In the **continuous mode**, the device must be stopped with the **STOP** key.

However, you can also select therapy durations of **1 to 59 minutes in steps of 1 minute** and of **1 to 24 hours in steps of 30 minutes.**

When the time has elapsed, the device switches automatically off and stops in the middle between the set limit values.

In this case, a circle replaces the clock symbol. The circle fills as the therapy time progresses.

■ **speed**

The speed can be adjusted between 5 % and 100 % in steps of 5 %.
default setting: 50 %

■ **new patient**

With this function, the CPM device will move to the home position. Select the function and press the **START** key. The device enters the home position and existing therapy parameters will be deleted.

On **ARTROMOT®-SP3 devices with a patient chip card** the factory defaults are restored. All values stored on the chip card will be deleted.

The carriage stops in the home position, dorsal extension / plantar flexion = 0° and inversion / eversion = 5°.

The "new patient" function (home position) selects the following settings:

- dorsal extension:	20°
- plantar flexion:	- 20°
- inversion:	- 5 °
- eversion:	15°
- pauses:	0
- timer:	continuous operation

continued on next page

- speed: 50 %
- reverse on load - motor A: 25
- reverse on load - motor B: 25
- motor A: ON
- motor B: ON
- synchronized mode: enabled
- total therapy time: 0
- special functions: disabled

LEVEL 3

■ **reverse on load - motor A (safety circuit)**

In the **synchronized mode**, the carriage automatically moves to the middle position when the patient's resistance (load) exceeds the set value.

In the **non-synchronized mode**, the carriage automatically moves in the opposite direction when the patient's resistance (load) exceeds the set value.

Adjustable levels for reverse on load feature: 1 - 25 at level 1, very little resistance will cause the device to reverse; at level 25, a high resistance is required to initiate the reversal.
default setting: level 25

■ **reverse on load - motor B (safety circuit)**

In the **synchronized mode**, the carriage automatically moves to the middle position when the patient's resistance (load) exceeds the set value.

In the **non-synchronized mode**, the carriage automatically moves in the opposite direction when the patient's resistance (load) exceeds the set value.

Adjustable levels for reverse on load feature: 1 - 25 at level 1, very little resistance will cause the device to reverse; at level 25, a high resistance is required to initiate the reversal.
default setting: level 25

⚠ Caution

Patient hazard – The reverse on load feature is a safety measure to protect the patient in the event of cramps, spasms, locked joints and similar situations. The manufacturer cannot be held liable for misuse of this feature.

■ **motor A ON/OFF** ⊙ A

To allow an isolated movement, the motors can individually be turned on and off. Motor A performs dorsal extension and plantar flexion movement, motor B performs eversion and inversion.

For an isolated eversion / inversion movement, set motor A to the appropriate position (dorsal extension / plantar flexion), then turn the motor off.

In the normal operating mode, the display will show the symbol for the dorsal / plantar movement disabled .
default setting: motor A ON

■ **motor B ON/OFF** ⊙ B

To allow an isolated movement, the motors can individually be turned on and off. Motor A performs dorsal extension and plantar flexion movement, motor B performs eversion and inversion.

For an isolated dorsal extension / plantar flexion movement, set motor B to the appropriate position (inversion / eversion), then turn the motor off.

In the normal operating mode, the display will show the symbol for the inversion / eversion movement disabled .
default setting: motor B ON

Note!

Please note that one motor (A or B) must always be turned on. Otherwise the display will show the message: ⒶOFFⒷ

LEVEL 4

■ **transport setting** →

With this function, the carriage will move to a position optimally suited for packing the CPM device. Select the function and press the START key. The carriage moves to the transport position. In the top left-hand corner of the display you will see → (also refer to chapter 6 Transport).

■ **synchronized/non-synchronized mode** A+B

Motors A and B can run in synchronized or non-synchronized mode.

synchronized:
Motors A and B perform a synchronized movement according to the ankle joint's physiological motion pattern:

From the middle position the carriage first goes to the maximum eversion value. Afterwards, the carriage will simultaneously move to the maximum inversion value and to the maximum plantar flexion value, and then simultaneously to the maximum dorsal extension value and to the value halfway between inversion and eversion. After reaching this position, the cycle restarts: maximum eversion at the same time as halfway between dorsal extension / plantar flexion, etc.

During operation the synchronized mode is indicated in the top left-hand corner by the symbol .

non-synchronized:
Both motors run independently of each other within the selected ranges of motion.

To enable the non-synchronized mode, disable the synchronized mode.

During operation the non-synchronized mode is indicated in the top left-hand corner by the symbol .
default setting:
synchronized mode enabled

⚠ Caution

Patient hazard –

The synchronized operation is recommended as a general rule. However, medical and/or therapeutic indications may call for the non-synchronized mode. In the non-synchronized mode, particular caution and attention on the part of the physician/therapist is required to rule out any risk for the patient.

■ **total therapy time** Σ

ARTROMOT®-SP3 without patient chip card

The total therapy time is the added sum of operating hours.

If the device is used by only one patient, this time is equivalent to the duration of all the patient's therapy sessions.

Under menu item "total therapy time" of **ARTROMOT®-SP3 models with chip card** you can view each patient's total therapy time (duration of all the patient's therapy sessions).

Deleting the stored therapy time
Press and hold the parameter key for 5 seconds or select the New Patient function.

■ **Service MENU**

For service purposes only, refer to Service Manual.

Reminder:

You save the set parameter values by pressing the **STOP** key.

5.4 Programming ARTROMOT®-SP3 Comfort

ARTROMOT®-SP3 Comfort devices offer further functions at two additional programming levels.

The programming levels are selected in the same way as on Standard models.

Programming levels 1, 2, 3 and 6 are identical with programming levels 1 to 4 of the Standard models.

With the default settingsall special functions are disabled.

The following treatment values, settings and information can be entered/viewed on the programming unit (22):

LEVEL 1:

- dorsal extension
- plantar flexion
- inversion
- eversion

MENU

LEVEL 2:

- pause
- therapy timer
- speed
- new patient

MENU

LEVEL 3:

- reverse on load - motor A
- reverse on load - motor B
- motor A ON/OFF
- motor B ON/OFF

MENU

LEVEL 4:

- warm-up protocol
- isolation program
- therapy documentation dorsal extension / plantar flexion
- therapy documentation inversion / eversion

MENU

LEVEL 5:

- stretching in dorsal extension
- stretching in plantar flexion
- stretching in inversion
- stretching in eversion

MENU

LEVEL 6:

- transport setting
- synchronized/ non-synchronized mode
- total therapy time
- service menu

5.5 Protocol details – Comfort models

- To access the programming level you need, press the **MENU key** repeatedly.
- The treatment parameters are selected with the different **parameter keys.**
- To change the treatment values, press the **+ / – keys**.
- To enable/disable a function, press the respective **parameter key** again.
- To save the entered values, press the **STOP key**.

With the **default settings** all **special functions are disabled**.

Note!

LEVEL 1: equivalent to level 1 of the Standard model (see: 5.3)

LEVEL 2: equivalent to level 2 of the Standard model (see: 5.3)

LEVEL 3: equivalent to level 3 of the Standard model (see: 5.3)

LEVEL 6: equivalent to level 4 of the Standard model (see: 5.3)

LEVEL 4

■ **warm-up protocol**

During warm-up, the patient will slowly become used to the set maximum dorsal extension / plantar flexion and inversion / eversion values, starting from the middle position.

The warm-up protocol starts in the middle between the two maximum values set for dorsal extension / plantar flexion and inversion / eversion.

In the beginning, the range of inversion / eversion motion increases with each cycle, until the programmed maximum values are reached after a total of 15 cycles. In this phase, motor A (dorsal extension / plantar flexion) is inactive.

Then the carriage stops again in the middle position and starts increasing the range of dorsal extension / plantar flexion motion with each cycle, until the programmed maximum values are reached after a total of 15 cycles. In this phase, motor B (inversion / eversion) is inactive.

After warm-up the device enters the normal mode.

During warm-up, the display will show the symbol in the upper, left-hand corner.
default setting: disabled

■ **isolation program** AIIIB

For this special function, both motors are turned on, but they will never move simultaneously.

These are the steps of the special function:

- At first motor B moves to the programmed maximum values for inversion and eversion for ten cycles, then it stops. In this phase, motor A is disabled (symbol for motor A:)
- Then motor A will move to the programmed maximum values for dorsal extension and plantar flexion for ten cycles and stops. The full cycle will start over with motor B. Motor B is disabled while motor A is operating (symbol for motor B:)
- The stop position at the end of each tenth cycle (for both dorsal extension / plantar flexion and inversion / eversion) can be selected in steps of 25% between 0% and 100% of the programmed maximum range of motion.
- Steps 1 and 2 can be repeated as often as needed. You can stop treatment with the STOP key; after the programmed therapy duration, it will stop automatically.

During warm-up, the display will show the symbol in the upper, left-hand corner.
default setting: disabled

Follow these steps to program the special function:

- Access menu level 4, then press the parameter key to select the special function.
- The display will show the symbol for the special function, its status (circle with or without check mark) as well as two boxes with the selected percentages for motor A and motor B stop positions.

  The circle appears in a box.
- Activate the function by pressing the "+" key (plus). Deactivate the function by pressing the "-" key (minus). In this case it is not possible to activate/deactive the function by pressing the parameter key again.

- A check mark appears in the circle which means that the function is active.
- Press the parameter key for the isolation program to select the upper number field where you enter the stop position for motor A.
- To modify the value, press the "+" (plus) or "-" (minus) key. Select 75%, for example.
- Press the parameter key again to select the lower number field where you enter the stop position for motor B.
- To modify the value, press the "+" (plus) or "-" (minus) key. Select 25%, for example.
- Save the programmed values by pressing the STOP key, then press the START key to begin the treatment.

This is what happens:

Dorsal extension / plantar flexion is treated ten times first (motor A). Motor B is positioned at 25% of the programmed range of motion for inversion and eversion.

Subsequently, inversion / eversion is treated ten times (motor B). Motor A is positioned at 75% of the programmed range of motion for dorsal extension and plantar flexion.

Note!

The percentage values can be modified only when the special function is enabled (check mark).

■ **dorsal extension / plantar flexion therapy documentation**

ARTROMOT®-SP3 Comfort devices with patient chip card have a special documentation function which provides a log of all therapy sessions.

The carriage run times as well as the range of motion of the sessions are recorded.

The collected data are presented graphically in the form of a coordinate system (X-axis = range of motion / Y-axis = time) where the upper curve illustrates the trend of the dorsal extension movement and the lower curve the trend of the plantar flexion movement.

■ **inversion / eversion therapy documentation**

ARTROMOT®-SP3 Comfort devices with patient chip card have a special documentation function which provides a log of all therapy sessions.

The carriage run times as well as the range of motion of the sessions are recorded.

The collected data are presented graphically in the form of a coordinate system (X-axis = range of motion / Y-axis = time) where the upper curve illustrates the trend of the eversion movement and the lower curve the trend of the inversion movement.

LEVEL 5

■ **stretching in dorsal extension**

With the special “stretching in dorsal extension” function the carriage gently stretches the joint by bending the foot upward.

Starting at the middle position the carriage will first move to the programmed plantar flexion value and then to the programmed dorsal extension value.

Subsequently the carriage reverses 5° towards plantar flexion and then moves very slowly back again to the

programmed dorsal extension value (display). After that it attempts to attain another 5 °, moving even slower than before (display).

If a high resistance toward the additional 5 ° is sensed, the reverse on load function is automatically activated and the carriage moves in the opposite direction.

This stretch cycle is repeated ten times.

After that the carriage moves to the programmed maximum plantar flexion value and restarts the dorsal extension stretch cycle.
default setting: disabled

Note!

- If a pause is programmed when you enable the function, the carriage will stop for the duration of the pause each time the maximum stretching value is attained.
- Enabling the stretching in dorsal extension function automatically disables motor B. The only movement performed is dorsal extension / plantar flexion.
- It is not possible to combine a second stretching function with the special function "stretching in dorsal extension".
- During operation the display will show the symbol .

■ stretching in plantar flexion

With the special "stretching in plantar flexion" function the carriage gently stretches the joint by bending the foot downward.

Starting at the middle position the carriage will first move to the programmed dorsal extension value and then to the programmed plantar flexion value.

Subsequently the carriage reverses 5° towards dorsal extension and then moves very slowly back again to the programmed plantar flexion value (display). After that it attempts to attain another 5°, moving even slower than before (display).

If a high resistance toward the additional 5° is sensed, the reverse on load function is automatically activated and the carriage moves in the opposite direction.

This stretch cycle is repeated ten times.

After that the carriage moves to the programmed maximum dorsal extension value and restarts the plantar flexion stretch cycle.
default setting: disabled

Note!

- If a pause is programmed when you enable the function, the carriage will stop for the duration of the pause each time the maximum stretching value is attained.
- Enabling the plantar flexion stretch function automatically disables motor B. The only movement performed is dorsal extension / plantar flexion.
- It is not possible to combine a second stretching function with the special function "stretching in plantar flexion".
- During operation the display will show the symbol .

■ stretching in inversion

With the special "stretching in inversion" function the carriage gently stretches the joint towards the inside.

Starting at the middle position the carriage will first move to the programmed eversion value and then to the programmed inversion value.

Subsequently the carriage reverses 5° towards eversion and then moves very slowly back again to the programmed inversion value (display for the right foot and for the left foot). After that it attempts to attain another 5°, moving even slower than before (display for the right foot and for the left foot).

If a high resistance toward the additional 5° is sensed, the reverse on load function is automatically activated

and the carriage moves in the opposite direction.

This stretch cycle is repeated ten times.

After that the carriage moves to the programmed maximum eversion value and restarts the inversion stretch cycle.
default setting: disabled

Note!

- If a pause is programmed when you enable the function, the carriage will stop for the duration of the pause each time the maximum stretching value is attained.
- Enabling the stretching in inversion function automatically disables motor A. The only movement performed is inversion / eversion.
- It is not possible to combine a second stretching function with the special function "stretching in inversion".
- During operation the display will show the symbol .

■ **stretching in eversion**

With the special “stretching in eversion” function the carriage gently stretches the joint towards the outside.

Starting at the middle position the carriage will first move to the programmed inversion value and then to the programmed eversion value.

Subsequently the carriage reverses 5° towards inversion and then moves very slowly back again to the programmed eversion value (display for the right foot and for the left foot). After that it attempts to attain another 5°, moving even slower than before (display for the right foot and for the left foot).

If a high resistance toward the additional 5° is sensed, the reverse on load function is automatically activated and the carriage moves in the opposite direction.

This stretch cycle is repeated ten times.

After that the carriage moves to the programmed maximum inversion value and restarts the eversion stretch cycle.
default setting: disabled

Note!

- If a pause is programmed when you enable the function, the carriage will stop for the duration of the pause each time the maximum stretching value is attained.
- Enabling the stretching in eversion function automatically disables motor A. The only movement performed is inversion / eversion.
- It is not possible to combine a second stretching function with the special function "stretching in eversion".
- During operation the display will show the symbol .

Reminder:

You save the selected parameter values by pressing the **STOP** key.

6. Care, Maintenance, Transport, Conversion

6.1 Care

⚠ Warning

Shock hazard – Remove the power cord from the wall outlet before cleaning.

Shock hazard, equipment damage – Liquids must not enter the device or the programming unit.

- ARTROMOT®-SP3 can be disinfected by **wiping down** with a disinfectant. Thus, it complies with the special hygiene standards for medical technical equipment.

- **The frame** and the removable **leg supports** can be cleaned with common **disinfectants** and **mildhousehold detergents.**

- Only use a **damp cloth** to wipe the CPM device down.

⚠ Caution

Equipment damage –

– The plastic material used is not resistant to mineral acids, formic acid, phenols, cresols, oxidants and strong organic or inorganic acids with a pH value below 4.

– Use only clear disinfectants to prevent discoloration of the device.

– Do not expose the CPM device to strong ultraviolet radiation (sunlight) and fire.

6.2 Maintenance (fuse replacement)

Check before each use

Visually inspect the device for signs of mechanical damage before each use.

If you detect damage or malfunctions that may impair the safety of the patient or of the operator, have the device repaired before using it.

Technical inspections

For safety, the devices require regular maintenance. To maintain the functional and operational safety, check all components for damage and loose connections at least once a year.

These checks should be performed by persons with adequate training and experience. Damaged and worn parts must immediately be replaced with original spare parts by authorized staff.

The inspections can be carried out by ORMED Technical Service within the framework of a service agreement.

The device does not require additional regular maintenance.

Fuse replacement

⚠ Warning

Patient hazard, equipment malfunction and damage –

The replacement of fuses must be referred to specialists as defined in IEC 60364 or other applicable standards (e.g. biomedical technicians, electricians, electronics installers).

Fuses used must be T1A fuses.

Before replacing fuses, turn off the ARTROMOT®-SP3 and disconnect the device from the power line.

Use an appropriate tool to remove the fuse holder situated between the power switch and the power connector (Fig. 1). Replace the fuses and reinsert the fuse holder (Fig. 2). Ensure that the fuse holder properly locks into place.

Fig. 1

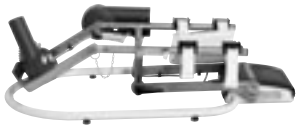
Fig. 2

6.3 Transport

The following operating steps must be completed before transporting the ARTROMOT®-SP3:

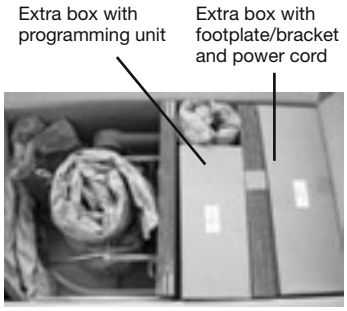
1. Activate the “transport setting” function → in the menu (see also 5.3) and start the ARTROMOT®-SP3.
2. Remove the footplate (7) as well as its bracket (11). To do so, simply pull it from the square-end guide at motor B. (Fig. G)
3. For transport of the device, motor B must be mounted on the right side of the moving bracket (15) (marked R). Refer to section 6.4 Conversion, if required.
4. Turn off the ARTROMOT®-SP3 power switch.
5. Disconnect the power cord and the programming unit.
6. Relieve the strain on the carriage by lifting it a little at the moving bracket for dorsal extension / plantar flexion (15) and open the clamping lever which adjusts the inclination of the carriage (5). Select an angle where the carriage is parallel with the adjusted height. Tighten the clamping lever to lock the carriage in this position.

7. Again lift the moving bracket for dorsal extension / plantar flexion (15) a little to remove the strain. Then loosen the locking device for the height adjustment by simultaneously pressing the two black pins of the lokking device together (19). Select a height where the locking pins engage in the top hole (marked: Transport).



8. Only use the original shipping box for transporting the device. ORMED GmbH & Co. KG cannot be held liable for transport damage, if the device was not shipped in its original shipping box.
9. Pack the programming unit (22) in the supplied box.
10. Place the footplate bracket (11) with the footplate (7) and the power cord in the extra box provided.

11. Place the ARTROMOT®-SP3 at the bottom of the shipping box. Then pack the two extra boxes for the programming unit and the footplate + bracket in the shipping box along with the padding material, as shown below.



6.4 Conversion

The ARTROMOT®-SP3 can be used on the left and on the right ankle joint. However, the device must be converted first. This is done very quickly.

1. Activate the “transport setting” function → in the menu (see also 5.3) and start the ARTROMOT®-SP3.
2. Remove the footplate (7) as well as its bracket (11). To do so, pull it from the square-end guide at motor B. (Fig. G)
3. Loosen thumbscrew (12) used to mount motor B to the moving brakket (15). Then pull the motor upward and remove (Fig. H).
4. Mount motor B on the opposite side of the carriage, using the thumbscrew.

5. Push the footplate bracket into the square-end aperture on motor B. Observe the marks: red dot on square rod of the footplate bracket to match red dot on square-end aperture on motor B, mark L or R on the footplate bracket to match mark L or R on the motor housing

Note!

- To assist in the conversion, motor B is equipped with a side identification function.

  The following symbols may appear on the display during conversion: (example) conversion from left to right:

  motor on the left-hand side:

  motor removed from bracket: Ⓑ?

  conversion to the right-hand side completed:

- If, after the conversion, the footplate bracket and thus the footplate is at an inadmissible angle, the display shows:

  START

  Please press the START key and the carriage will automatically move to the permitted range and stop.

English

7. Environmental Protection Statement

The product described in this operation manual must not be disposed of with unsorted household or municipal waste. It requires separate disposal. Please contact ORMED for information about the possible recycling of the product.

8. Specifications

Input ratings:	100 – 240 V AC / 50 – 60 Hz
Current consumption:	850 - 370 mA
Fuses:	2 x T1A (slow-blow)
Protection class:	I
Applied part:	type B
Max. load on carriage:	20 kg

Dimensions (transport position):

Length:	78.0 cm
Width:	42.0 cm
Height:	39.5 cm

Weight:	11 kg
Materials used:	ABS, POM (Delrin 100), PUR, PA, FR4, aluminum, stainless steel, brass
MDD:	class 2a
Standards compliance:	IEC 60601-1:1988 + A1:1991 + A2: 1995
Certification:	ANSI / UL 60601-1 CAN / CSA C22.2 No. 601.1
EMC (electromagnetic compatibility)	IEC 60601-1-2:2001

Ambient conditions (storage, transport)

Temperature:	-24 °C to +60 °C (-12 to +140 °F)
Relative humidity:	20% to 85%
Atmospheric pressure:	700 hPa to 1060 hPa

Ambient conditions (operation)

Temperature:	+10 °C to +40 °C (50 to +104 °F)
Relative humidity:	30% to 75%
Atmospheric pressure:	700 hPa to 1060 hPa

Subject to change without notice (01/07)

9. IEC 60601-1-2:2001

The **ARTROMOT®-SP3** device is subject to particular precautions regarding electromagnetic compatibility (EMC). The device must be installed and put into service strictly in compliance with the EMC directives put forth in the accompanying documents.

Portable and mobile RF communication systems may affect the **ARTROMOT®-SP3** device.

The **ARTROMOT®-SP3** device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, **ARTROMOT®-SP3** should be observed to verify normal operation in the configuration in which it will be used.

If you detect damage or malfunctions that may impair the safety of the patient or of the operator, have the device repaired before using it.

If it is necessary to replace assemblies or cables, only the manufacturer's original parts must be used to ensure continued compliance with EMC requirements after repair. This requirement applies to the power supply unit, cables and cable lengths, drive unit consisting of the motor and the control system, the programming unit incl. the coiled cable and the connector.

The equipment name **ARTROMOT®-SP3** used below always designates all device models such as ARTROMOT®-SP3, ARTROMOT®-SP3 comfort, ARTROMOT®-SP3 with chip card, ARTROMOT®-SP3 comfort with chip card.

9.1 Electromagnetic emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

ARTROMOT®-SP3 is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the **ARTROMOT®-SP3** device is used in such an environment.

Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions to CISPR 11	Group 1	**ARTROMOT®-SP3** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions to CISPR 11	Class B	**ARTROMOT®-SP3** is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions to IEC 61000-3-2	not applicable	
Voltage fluctuations/flikker emissions to IEC 61000-3-3	not applicable	

9.2 Electromagnetic immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

ARTROMOT®-SP3 is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the **ARTROMOT®-SP3** device is used in such an environment.

Immunity test	**IEC 60601-test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) to IEC 61000-4-2 ± 6 kV contact	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst to IEC 61000-4-5 ± 2 kV for power supply lines	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power should be that of a typical commercial or hospital environment.
Surges to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines to IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for ½ cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	< 5 % U_T (> 95 % dip in U_T) for ½ cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	Mains power should be that of a typical commercial or hospital environment. If the user of the **ARTROMOT®-SP3** device requires continued operation during power mains interruptions, it is recommended that the **ARTROMOT®-SP3** device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment. Portable and mobile RF communications equipment are used no closer to any part of the **ARTROMOT®-SP3** device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

ARTROMOT®-SP3 is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the **ARTROMOT®-SP3** device is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
			Recommended separation distance:
Conducted RF to IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	$d = 1.2\sqrt{P}$
Radiated RF to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
			$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and[d] is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], is less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **ARTROMOT®-SP3** device is used exceeds the applicable RF compliance level above, the **ARTROMOT®-SP3** device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **ARTROMOT®-SP3** device.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

9.3 Recommended separation distances between portable and mobile RF communications equipment and the ARTROMOT®-SP3 device.

The **ARTROMOT®-SP3** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **ARTROMOT®-SP3** device can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **ARTROMOT®-SP3** device as recommended below, according to the maximum output power of the communications equipment

rated maximum output power of transmitter W	separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: For calculation of the recommended separation distance of transmitters in the frequency range from 80 MHz to 2.5 GHz an additional factor of 10/3 was taken into account to reduce the probability of mobile/portable communications equipment brought into the patient environment by accident causing any malfunction.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

10. Contact

We would be happy to answer any questions you may have about our products or services.

- **ORMED international**
  Please contact your local dealer or the ORMED headquarters in Germany.
- **Headquarters Germany**
  ORMED GmbH & Co. KG
  Merzhauser Strasse 112
  79100 Freiburg - Germany
  Tel. +49 761 45 66-01
  Fax +49 761 45 66 55-01
- **Internet**
  www.ormed.de
  e-mail: info@ormed.de

Warranty:
2 years (mechanical parts)
2 years (electronics)

Sales:
ORMED GmbH & Co. KG
Merzhauser Strasse 112
D-79100 Freiburg

11. Technical service

11.1 Technical hotline

Do you have any technical questions?
Do you need technical service?

Telephone: +49-180-5-1 ormed de
+49-180-5-1-67 63 33
Fax: +49-180-5-3 ormed de
+49-180-5-3-67 63 33

11.2 Shipment

To prevent damage during transport, only use the original shipping box. These boxes can be obtained from ORMED.

Before packing the CPM device, set it to the transport position (see chapter 6.3).

11.3 Spare parts

Refer to the Service Manual for the most recent list of spare parts.

When ordering spare parts, always specify:

- item
- description
- part number
- quantity
- serial number of the CPM device

Note!

Refer repairs to authorized, specially trained staff.

ORMED GmbH & Co. KG offers service training for your personnel.

Surcharges may apply in certain cases to spare parts ordered in low quantities.

Im Einzelfall bitte Mindermengenzuschläge für Ersatzteile beachten.

item	description	part no.	qty
1.	patient chip card	0.0037.035	
2.	marker pen for patient chip card	0.0031.006	

English

DECLARATION OF CONFORMITIY

Declaration of conformity

In compliance with the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, the company

ORMED GmbH & Co. KG
Merzhauser Straße 112
D-79100 Freiburg

declares that the products of the product line

ARTROMOT® (see Annex)

fulfill the requirements of the Council Directive 93/42/EEC of 14 June 1993, Annex II as well as the essential requirements of Annex I.

CE
0297

Freiburg, January 24th, 2007

- QA Management Representative-

Anhang:

ARTROMOT®-S2 *PRO*
ARTROMOT®-S3
ARTROMOT®-S3 Comfort
ARTROMOT®-K1
ARTROMOT®-K2
ARTROMOT®-K2 *PRO*
ARTROMOT®-K2 *PRO* Chip
ARTROMOT®-K3
ARTROMOT®-K4
ARTROMOT®-SP2
ARTROMOT®-SP3
ARTROMOT®-E2
ARTROMOT®-E2 compact

Piktogrammübersicht Standard Versionen ARTROMOT®-SP3

Symbol Overview standard models ARTROMOT®-SP3

EBENE 1/LEVEL 1

Dorsalextension
dorsal extension

Plantarflexion
plantar flexion

Inversion
inversion

Eversion
eversion

EBENE 2/LEVEL 2

Pause
pause

Timer
timer

Geschwindigkeit
speed

Neuer Patient
new patient

EBENE 3/LEVEL 3

Lastumkehr Motor A
load reversal motor A

Lastumkehr Motor B
load reversal motor B

Motor A Ein/Aus
motor A ON/OFF

Motor B Ein/Aus
motor B ON/OFF

EBENE 4/LEVEL 4

Transporteinstellung
transport setting

Betriebsart
Synchron/Asynchron
synchronized/non-synchronized mode

Gesamttherapiezeit
total therapy time

Service-Menü
service menu

Piktogrammübersicht Comfort Versionen ARTROMOT®-SP3

Symbol Overview comfort models ARTROMOT®-SP3

EBENE 1/LEVEL 1

Dorsalextension

dorsal extension

Plantarflexion

plantar flexion

Inversion

inversion

Eversion

eversion

EBENE 2/LEVEL 2

Pause

pause

Timer

timer

Geschwindigkeit

speed

Neuer Patient

new patient

EBENE 3/LEVEL 3

Lastumkehr Motor A

load reversal motor A

Lastumkehr Motor B

load reversal motor B

Motor A Ein/Aus

motor A ON/OFF

Motor B Ein/Aus

motor B ON/OFF

EBENE 4/LEVEL 4

Aufwärmprogramm

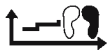
warm up protocol

Isolationsprogramm

isolation protocol

Therapieverlaufs-dokumentation Dorsal-/Plantarflexion

dorsal extension / plantar flexion therapy documentation



Therapieverlaufs-dokumentation Inversion/Eversion

inversion / eversion therapy documentation

EBENE 5/LEVEL 5

Dehnung Dorsalextension

stretching in dorsalextension

Dehnung Plantarflexion

stretching in plantar flexion

Dehnung Inversion

stretching in inversion

Dehnung Eversion

stretching in eversion

EBENE 6/LEVEL 6

Transporteinstellung

transport setting

Betriebsart Synchron/Asynchron

synchronized/non-synchronized mode

Gesamttherapiezeit

total therapy time

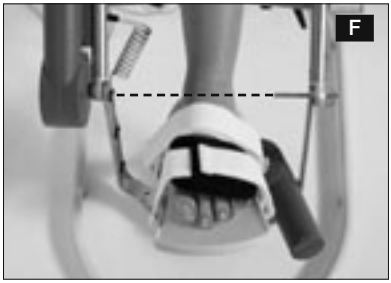
Service-Menü

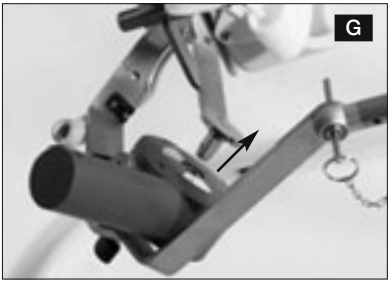
service menu

ARTROMOT®-SP3 Abbildungen zur Einstellung

ARTROMOT®-SP3 setup illustrations
Figures illustrant le régage
Ilustraciones de los diferentes ajustes

Figure per la messa a punto
Afbeeldingen voor het instellen





MOT-319-3/07

DIN EN 13485 ORMED Nr. 018 829-01

ORMED GmbH & Co. KG • Merzhauser Straße 112 • D-79100 Freiburg
Tel +49 761 4566-01 • Fax +49 761 4566-5501 • www.ormed.de
E-Mail: info@ormed.de

ORMED
IDEEN BEWEGEN